

February 21, 2023

**VIA ECF**

Honorable Edward S. Kiel, U.S.M.J.  
United States District Court, District of New Jersey  
United States Post Office & Courthouse  
Federal Square, Courtroom 8  
Newark, New Jersey 07101

**Re: Joint Status Conference Letter**  
***U.S. ex rel. Silbersher v. Janssen Biotech Inc.***  
**Civil Action No. 19-12107(KM-ESK)**

Dear Judge Kiel:

Counsel for the parties in the above-referenced matter respectfully submit this joint letter to advise the Court of the status of discovery in this matter in advance of the February 23, 2023 status conference.

**I. Party Discovery**

Since the last conference with the Court, Defendants have made two additional productions, for a total of eleven productions since the parties' August 17, 2022 meet-and-confer. These eleven productions comprise 21,952 documents and a total of 116,666 pages. Previously, Defendants produced 78,729 documents that were produced during the course of, or originated from, the prior ANDA Litigations, totaling 5,404,397 pages. Defendants have been producing documents on a rolling basis and expect to substantially complete production by February 28, 2023.

Relator has responded to Defendants' first and second sets of Requests for Production ("RFPs") and Defendants' first set of Interrogatories, producing a total of 100 documents comprising 2,498 pages. Relator has maintained objections to certain of Defendants' discovery requests. On December 9, 2022, the parties met and conferred on Defendants' outstanding RFPs and Relator's objections to those RFPs. During the January 6, 2023 status conference, Defendants stated their intention to bring their remaining discovery issues to the Court for resolution. On February 16, Defendants provided Relator with a draft letter setting forth their position. The parties are currently preparing a joint letter setting forth each party's position to this Court to resolve certain of Relator's objections. The parties expect to submit this letter prior to the February 23 status conference.

On February 8, 2023, Defendants served on Relator a second set of interrogatories. Relator intends to answer these interrogatories on or before March 10, 2023.

Relator believes that he has been unable to resolve certain objections raised by Defendants concerning the time period to be searched and produced in response to certain of Relator's document requests; however, Defendants are not clear on what specific issues remain

Honorable Edward S. Kiel, U.S.M.J.  
February 21, 2023  
Page 2

related to these requests. Defendants thus believe it would be appropriate for Relator to meet and confer regarding these objections before declaring an impasse. Relator also intends to meet and confer with Defendants concerning additional custodians beyond those identified by Defendants in their July 7, 2021 Rule 26 disclosure, as well as appropriate search terms for those custodians. Defendants have also objected to certain requests on the ground of privilege, and Relator intends to serve interrogatories and to meet and confer with Defendants concerning Defendants' assertion of the attorney-client privilege and work-product doctrine. Assuming that Defendants substantially complete production of documents responsive to Relator's first set of requests by February 28, 2023, Relator intends to promptly initiate and conclude meet and confer efforts by March 28, 2023. Defendants reserve the right to object based on Relator's lack of diligence in attempting to negotiate or even engage with Defendants regarding these points, because Relator has not previously sought to meet and confer regarding custodians, search terms, or privilege objections.

The parties have not yet taken any depositions, but Relator intends to schedule an initial round of depositions beginning April 1, 2023.

## **II. Non-party Discovery**

On November 28, 2022, the Court denied Relator's motion to compel Defendants to produce confidential material belonging to certain generic-drug manufacturers (Mylan and Apotex) and provided to Defendants in the ANDA Litigation, as well as Relator's motion to amend the operative confidentiality order to allow Relator access to certain, highly confidential designated information. Based on the Court's decision, Relator has been negotiating with various generic-drug manufacturers for the production of discrete categories of documents set forth in proposed subpoenas previously provided to each of them.

Relator has concluded its negotiations with Amneal and Teva and has not been able to reach agreement. Accordingly, Relator intends to file motions to compel compliance with subpoenas that counsel for those generic manufacturers have agreed to accept. Relator served these subpoenas on February 15, 2023. Relator is still negotiating in good faith with the other generic manufacturers, including Dr. Reddy's Laboratories, Hikma, Mylan, Apotex, Citron, Wockhardt, and MSN Laboratories. Relator intends either to reach agreement with the generic manufacturers by March 15, 2023, or initiate steps to bring any discovery dispute to the Court for resolution.

Defendants also intend to seek documents from certain generic manufacturers., Defendants proposed to Relator that the parties provide a single set of requests to these generic manufacturers in the pursuit of efficiency. Because of Relator's ongoing attempts to secure agreement with generic manufacturers based on a narrowed set of requests, Relator declined Defendants' proposal. Defendants are accordingly preparing their own set of document requests to serve on the generics.

Honorable Edward S. Kiel, U.S.M.J.  
February 21, 2023  
Page 3

### III. Revised Discovery Schedule

During the January 6, 2023 status conference, the Court asked the parties to address the possible need to update the current discovery schedule (ECF No. 213) at the February 23 status conference. Relator believes that the current discovery schedule should be updated to realistically reflect the remaining discovery that needs to be completed, and to account for the delays resulting from discovery disputes, discovery motions, and the fact that Defendants have not yet substantially completed production of documents responsive to Relator's first set of requests (served nearly a year ago). Relator believes that an updated schedule will facilitate better planning and scheduling going forward.

Currently, targeted summary judgment motions must be filed no later than April 7, 2023, and fact discovery closes on August 7, 2023. The parties have not yet met and conferred concerning the precise issues they intend to present to the Court for early summary judgment, and Relator believes that the current April 7 deadline for early summary judgment motions is too early for the parties adequately to present yet to be specified issues to the Court for summary adjudication.

Given the complexity of this case, the substantial third-party discovery issues that remain unresolved, and the amount of discovery that still need to be completed, Relator believes the Court should update the current discovery schedule by extending the current deadlines by six (6) months, such that:

- Early summary judgment motions must be filed no later than October 2, 2023;
- Fact discovery must be completed by February 7, 2024.
- Expert discovery, which is currently scheduled to commence with Relator's expert reports to be served 60 days after the close of fact discovery, would be extended *de facto*.

Defendants disagree, and believe that any request to modify the deadlines for fact discovery is premature. More than five months remain in the year-long fact discovery period previously set by the Court. As noted above, Defendants intend to substantially complete their document production by February 28, 2023. Despite Defendants producing more than 21,000 documents since August 2022, Relator has not attempted to respond to Defendants Responses and Objections—which Defendants provided to Relator on April 25, 2022—or to negotiate with Defendants on the substance of their document production beyond the time period Relator contended was relevant to certain of his RFPs. To the extent Relator believes significant fact discovery remains, it is a problem of his own creation.<sup>1</sup>

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<sup>1</sup> Defendants also note that Relator's request to extend the deadlines for fact discovery is *de facto* a request to also extend the deadlines for his expert discovery, which, because it proceeds first in the calendar, can proceed in parallel with fact discovery. Although Defendants believe an extension of the fact discovery period is premature at this time, any extension of fact discovery

Honorable Edward S. Kiel, U.S.M.J.  
February 21, 2023  
Page 4

#### IV. Government Discovery

As the parties previously reported, Defendants have served subpoenas duces tecum on (1) the United States Patent and Trademark Office, (2) the United States Department of Veterans Affairs (“VA”), and (3) the Centers for Medicare and Medicaid Services. Defendants continue to discuss the subpoenas with all three agencies. Defendants are hopeful that they will not need court intervention regarding the VA, and it is still unclear if they will need court assistance as to the other agencies.

#### V. Other Issues

The parties agree that no issues other than those described above need be addressed at this time.

Respectfully yours,

#### SILLS CUMMIS & GROSS P.C.

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should be met with at least a commensurate extension of the period allotted to Defendants for preparing their rebuttal expert reports (currently allotted for 60 days) in response to Relator’s expert reports.